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PURPOSIVE INTERPRETATION AND THE REGULATION OF TECHNOLOGY: LEGAL CONSTRUCTS, LEGAL FICTIONS, AND THE RULE OF LAW

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ABSTRACT

Blackstone and Bentham held opposing views about the legitimacy of legal fictions. Blackstone felt that legal fictions could be useful devices, whereas Bentham held them in complete contempt. This paper aims to partially reconcile these two positions. It distinguishes between two types of fictions in the law, one described as a fiction for the purposes of the law and the other as a fiction about the law. Examples are drawn from medical and patent law to highlight situations where the law has been used in a purposive manner to achieve fundamental values, compared to where the law has been distorted to realise an aim incompatible with the rule of law. Some implications for the standard doctrine of legal fictions are drawn.

Introduction

In the *Pro-Life Alliance* case,¹ the House of Lords resorted to purposive construction to bring the use and storage of human embryos produced by somatic cell nuclear transfer (SCNT) (the so-called ‘Dolly the sheep technique’) under the remit of the Human Fertilisation and Embryology Act 1990 (HFE Act). Although their Lordships agreed that SCNT was not an act of fertilisation, we will argue that it is a logical implication of the purposive reasoning underlying this construction that SCNT is to be regarded as a process of fertilisation and enucleated eggs and somatic nuclei used in such a process are to be regarded as gametes. But, it might be retorted, ‘SCNT is not a process of fertilisation and enucleated eggs and somatic nuclei are not gametes! Such a move involves a “legal fiction”’. However, what we make of this depends on our attitude towards legal fictions. So, for example, William Blackstone held that legal fictions are useful devices that enable courts to overcome obstacles to achieving justice,²

while Jeremy Bentham had nothing but contempt for them. For him, every legal fiction ‘affords presumptive and conclusive evidence of moral turpitude in those by whom it was invented and employed’³ and is of no more use to justice than ‘swindling is to trade’.⁴

But are all ‘fictions’ deployed in the law alike? Our principal aim in this paper is to draw attention to an important difference between two ways in which a fictional element can be introduced into what might loosely be termed ‘a legal fiction’, which might at least partially reconcile the positions of Blackstone and Bentham. This distinction is between cases where the fiction that the law employs is a fiction from the perspective of science, or common understanding, but is a construction necessary to achieve fundamental legal values, and cases where the fiction is a fiction about the very thing that the law purports to value.

In the first part of this paper, we will elucidate this distinction by contrasting the ‘fiction’ we impute in the *Pro-Life Alliance* case with that involved in s.6 of the Human Tissue Act 2004 (HTA) (according to which, under conditions specified by regulations, persons unable to consent to use of storage of their tissue are to be deemed to have consented to it). We will argue that the former is a fiction for the purposes of the law and fits Blackstone’s characterisation, while the latter is a fiction about the law which merits Bentham’s vituperative comments. We will maintain, further, that the idea that SCNT is a process of fertilisation is not legally speaking a fiction at all, but a fact in English law (though it is, indeed, a fiction from the point of view of science or common understanding), whereas deemed consent in the absence of the ability to consent is a genuine legal fiction as it involves distortion of the values that consent has in the law. Our general thesis will be that legal facts are to be determined by legal purposes. However, we will argue further that it is necessary to distinguish contingent from essential legal purposes, and only distortions of essential legal purposes (which we will divide into two kinds, procedural and substantive) are necessarily inimical to respect for the rule of law and justify Bentham’s antagonism. We argue that the HTA fiction falls into this category.

In the second part of this paper, we will attempt to apply our analysis to a number of cases in patent law: viz. treating (1) the process of revealing a genetic sequence that occurs in nature as inventive (necessary for patents to be granted) and not merely as a process of discovery; (2) whole genera of animals as patentable when animal varieties are not patentable under Article 53(b) of the European Patent Convention (EPC), and (3) fungi and cells as microbiological entities, thereby enabling an exemption from the provision of Article 53(b) EPC that patents may not be granted to essentially biological processes for the production of plants or animals.



We will conclude by drawing some implications for the standard doctrine of legal fictions.

PART ONE

The Pro-Life Alliance Case⁵

The HFE Act defines an ‘embryo’ as ‘a live human embryo where fertilisation is complete’⁶ including ‘an egg in the process of fertilisation’.⁷ This raises the question whether an embryo created by SCNT (where the nucleus of a somatic cell is inserted into an enucleated ovum) is an embryo under the Act. If it is, then use or storage of an embryo created by SCNT is regulated by the Act (under which it is made subject to a licence being granted by the Human Fertilisation Authority (HFEA)), otherwise use and storage of such embryos is unregulated by the Act.

This issue was the subject of a judicial review action taken by Bruno Quintavalle on behalf of the Pro-Life Alliance. At first instance, Crane J held that SCNT does not produce an embryo, because it does not involve an act of fertilisation.⁸ The Court of Appeal reversed this decision by implying a phrase into the relevant sub-section, which is to be read as defining an embryo as ‘a live human embryo where [*if it is produced by fertilisation*] fertilisation is complete’.⁹ The House of Lords agreed that SCNT is not an act of fertilisation¹⁰ but held that the HFE Act must be interpreted purposively in the light of subsequent developments. This purpose was to regulate human embryos created outside the body, rather than only embryos created by fertilisation. How, then, is s.1(1) to be read? According to Lord Bingham (with whose speech Lord Hoffman and Lord Scott agreed),

the four words [‘where fertilisation is complete’] were not intended to form an integral part of the definition of embryo but were directed to the time at which it should be treated as such. ... The essential thrust of section 1(1)(a) was directed to such embryos, not to the manner of their creation ...¹¹

Lord Steyn was prepared to accept the Court of Appeal’s attempt to read the words ‘if produced by fertilisation’ into s.1(1)(a), but preferred to treat the restrictive wording of s.1(1) ‘as merely illustrative of the legislative purpose’.¹² Lord Millet held that the words of s.1(1) were *not* intended to define ‘the word ‘embryo’ but to rather limit it to an embryo which is (i) live and (ii) human’.¹³

In line with this, s.1(1)(a) effectively means that the HFE Act applies to any entity that is *functionally* a human embryo (one that

could be implanted into a woman and develop into a human child). Such reasoning receives its justification from the Warnock Report, which provided the impetus for the HFE Act, which makes it clear that the Act was designed to protect 'the embryo of the human species' because it has 'a special status' albeit less than that of a living child or adult¹⁴ on the grounds that it has the potential to develop into a living child or adult.

Suppose, however, that their Lordships had accepted s.1(1) as a definition of an embryo. Would this mean that they would have had to hold that SCNT embryos were not regulated by the HFE Act? Only if (as they did) they agreed with Crane J that SCNT is not a process of fertilisation. But why should this be accepted? If the purpose of the Act is to protect functional embryos by whatever means they are created (which their Lordships' reasoning relies upon), and, at the same time, embryos are defined as created by a process of fertilisation, then whatever process creates a functional embryo is, *relative to this purpose* and in the context of this understanding, to be regarded as a process of fertilisation. Of course, *from a scientific perspective*, or from the perspective of common understanding or usage, SCNT might very well not be a process of fertilisation. But why should the law define things according to scientific understanding or purposes that are not essential legal? The reason why science would wish to distinguish the process of fertilisation as commonly understood from SCNT is that it is interested in understanding biological processes and functions, and for *these purposes* needs to understand these in terms of their biological differences. That SCNT is a different *biological* process from the union of sperm and ovum is what matters. However, for the purposes of the HFE Act, such differences are not material. They only matter if they do not produce a functional embryo. The idea that SCNT is a process of fertilisation is fictional only relative to a definition for scientific purposes. Relative to the law's purpose of protecting functional embryos howsoever created, the creation of an embryo by SCNT is a process of fertilisation when embryos are defined as produced by fertilisation. Indeed, relative to this purpose, it is a legal *fact* (not a legal fiction at all) that SCNT is a process of fertilisation, even if it is a scientific fiction.¹⁵ In short, the idea that SCNT is a process of fertilisation is only a scientific fiction for the law's purposes but not therefore a legal fiction, unless it is essential to the law's purpose that scientific purposes be achieved thereby. But such a proviso does not apply here.

This line of reasoning, we submit, does no violence to the HFE Act and the principle of fidelity to Parliament's intentions. It neither requires us to read words into s.1(1), nor does it require us to treat this provision as not providing a definition, when it is natural to



regard it as such. In addition, it avoids various lacunae or gaps in the Act that are left by not regarding SCNT as a process of fertilisation (and, correlatively the enucleated ovum and the somatic nucleus as gametes in the context of the process of SCNT). For example, the Act requires the written consent of gamete providers for the creation and use of an embryo,¹⁶ but, unless SCNT is regarded as a process of fertilisation (and the somatic nucleus and enucleated ovum regarded as gametes), this provision will not apply. Also, the Act sets a time-limit for keeping or using embryos, set by s.3(3)(a) as at 'the appearance of the primitive streak', with s.3(4) providing that 'the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed'. The appeal courts' reasoning renders this section inapplicable as no gametes are mixed, so the Act sets no limits on the time for which an embryo produced using the Dolly technique can be kept or used. However, under our imputation, the 14 days begins when the cloned embryo is created, as it is then that what are functionally gametes are mixed.¹⁷

Section 6, HTA 2004

According to s.1(1)(d) and (f) of the HTA 2004, storage for use for a purpose specified in Part 1 of Schedule 1 (which includes transplantation) of any relevant material which has come from a human body, and use for such a purpose, are lawful if done with 'appropriate consent.' Where the person is an adult and alive, 'appropriate consent' means the consent of the adult.¹⁸

Now, according to s.5(1), performance of an activity to which s.1(1) applies constitutes an offence unless done with a reasonable belief that consent has been given or that s.1(1) does not apply to the activity. So, appropriate consent is, subject to this proviso, both necessary and sufficient for the lawfulness of activities to which s.1(1)(d) and (f) apply. This statement might appear to be contradicted by s.7, which is headed 'Powers to dispense with the need for consent'. However, s.7(3) and (4) makes it clear that under the conditions laid down by s.7, consent is to be deemed to be given. As such, s.7 does not create exemptions from the consent requirements of s.1 and s.5, but merely specifies that these requirements will be satisfied when consent has not actually been given. In other words, s.7 provides that the requirements for consent under the Act will be satisfied in certain circumstances where consent has not been given.

To like effect, according to s.6

Where

- (a) *an activity of a kind mentioned in section 1(1)(d) or (f) involves material from the body of a person who—*
 - (i) *is an adult, and*
 - (ii) *lacks capacity to consent to the activity, and*
- (b) *neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State.*

With reference to this provision, Regulation 3(2)(a) of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 specifies that an adult who lacks capacity to consent to activities falling under s.1(1)(d) and (f) of the Act is deemed to have consented to these activities if they are carried out by a person who is acting in what he reasonably believes to be the incapacitated adult's best interests.

Now, to deem consent when consent has not been given or cannot be given is to resort to a fiction.¹⁹ There are, however, some important differences between this fiction and the fiction we have imputed in the *Pro-Life Alliance* case. The most important of these differences is that the putative fiction in the *Pro-Life Alliance* case is a device to ensure that what the law seeks to protect (functional embryos) is protected, the fiction of deemed consent, on the other hand, is a fiction about what the HTA 2004 ostensibly seeks to protect, viz., the autonomy of persons.²⁰ Unless this is the case, there is no need for appropriate consent (per s.1 and s.5) to be a necessary and sufficient condition for lawfulness under the Act.

This, however, raises problems. If autonomy is the essential value to be protected, then to deem it to be served when it cannot be served or has not been served is nothing short of deliberate obfuscation. If it is permissible to deem the purpose of the law to be served when it cannot be or is not served, then this, by being self-contradictory, not only deprives the law of all meaning but involves both the logical and moral absurdity of regarding a value as protected by its very violation. As Lon Fuller has most persuasively maintained,²¹ essential requirements of observance of the Rule of Law include that there be non-contradictory rules and that there be congruence between official action and declared rule. In the fiction of deemed consent, we have violation of both these requirements because the contradiction permits congruence with the rule to be constituted by its very non-congruence.

It should also be noted that, as a matter of general legal principle, this fiction is completely unnecessary. It would, at least in principle,



have been open to the legislator simply to have provided an exemption from the requirement for consent under the conditions under which the consent is to be deemed to be given (per s.6, and, by the same token, s.7). To do this would, clearly, require consent not to have been made a necessary and sufficient condition of lawful action.²² Now, if consent were, in the wider legal scheme of things, to have such a status, then this would not be an available option. However, this is not the case in the UK. The idea that there are public interest exemptions from the requirement for consent in relation to the use and disclosure of sensitive personal data and other invasions of a person's bodily and personal integrity is well-established in English case law and statutes.²³ Of course, subsequent to the Human Rights Act 1998, all UK legislation must be interpreted to be in conformity with the European Convention on Human Rights (ECHR) if it is possible to do so.²⁴ However, this does not remove this option. While it is arguable that Article 8(1) of the ECHR is engaged by the use and storage of human tissue,²⁵ and that there is a *prima facie* violation of Article 8(1) without the explicit consent of the source of the tissue,²⁶ Article 8(2) provides for an exemption from this requirement if a number of conditions laid down in Article 8(2) are satisfied.²⁷

Whether or not the conditions laid down in Regulation 3(2)(a) of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 would satisfy the requirements of Article 8(2) ECHR is moot. However, if we suppose that they would, then is it not arguable that, in practice, deeming consent under the conditions set by the Regulations rather than overriding it (which appeal to Article 8(2) involves) makes little difference? We think not. An important legal principle is at stake here, which has important practical implications. The principle at stake is the distinction between non-engagement of a right and the overriding of a right. If consent is deemed to be given, where consent would be sufficient to legitimate an action, then no further justification is required for the action. In the present case, to characterise the issue as a matter of consent having been given is, by implication, to deny the engagement of Article 8(1) ECHR, which implies that no justification is required in terms of Article 8(2). On the other hand, to characterise it as a matter of exemption is to recognise that Article 8(1) is engaged and that a justification in terms of Article 8(2) is required. Of course, if the conditions under which consent is to be deemed to be given would satisfy the conditions imposed by Article 8(2), then the result will, consequentially, be the same. The practical problem, however, is that the need for such a congruence is denied by the deeming of consent, which has the effect that, while the issue of compatibility with the ECHR has not been removed, the ability of the UK courts to consider the matter is made more complicated. A conundrum is

created. For, surely, before the courts can consider whether Article 8(2) conditions are satisfied, they must determine that Article 8(1) is engaged. But since the Act implicitly denies that Article 8(1) is engaged, if the courts find that it is engaged they must consider the Act to be incompatible (in relation to which they can only make a declaration of incompatibility with Article 8(1)), but cannot proceed to consider the substantive issue of compatibility with Article 8(2). No doubt the courts would find a way around this; but it is difficult to see how a solution could be anything but ad hoc. In any event, the effect of deeming consent obscures the fact that the parameters to consider are those of Article 8(2) ECHR. This, in a society and legal system that purports to respect human rights, is not a matter of merely theoretical import.²⁸

As we have already intimated, certain formal and procedural conditions (such as congruence between declared rule and official action) are universal requirements of the rule of law. To argue that adherence to human rights values is such is much more contentious. Nevertheless, such substantive values can be so deeply embedded in a legal system that they can come to be regarded as requirements of the rule of law (hence essential legal values). While the UK is to a degree ambivalent about giving the values of the ECHR this status, there can be no doubt that the idea that human rights are fundamental rights/freedoms encapsulates this idea. It is implicit that for all civilised countries, human rights are part of the *ordre public*, and *ordre public* in this context is to be understood as that set of fundamental principles that underpin the legal system in a state.²⁹

With reference to the events that led to the HTA, the deemed consent provisions of the Act appear to be an attempt to satisfy two irreconcilable bodies of opinion. On the one hand, there is an increasingly vociferous lobby for the idea that consent is necessary and sufficient for all actions impinging on the private sphere of a person's body or personality to be ethical.³⁰ On the other hand, there is a body of opinion that denies this, and considers that there are circumstances in which consent is not necessary (and might also not be sufficient).³¹ Rhetorically, the legislature has sided with the former group. Yet, by permitting various actions without consent, the legislature has, in practical effect, sided with the latter group. In so doing, it has acted as though it believes that it will satisfy the former simply by stating that consent is necessary and sufficient for lawfulness. This is naïve. A rose by any other name smells just as sweet and rotten cabbages by any other name smell just as foul. And, to add another metaphor, actions speak louder than words. This will fool no-one and runs the risk of undermining respect for the law.



Blackstone and Bentham Again

Our analysis has focussed on two rather special cases. It is, therefore, not easy to draw confident generalisations. However, we suggest that the following premises may serve as the basis for a deeper analysis.

- (1) What is a legal fact as against a legal fiction is to be determined by definitions that are driven by the purposes to be served by the law.
- (2) Some purposes to be served by the law are essential to the rule of law in any legal system. While only natural lawyers would declare various substantive values to be conceptually connected to the rule of law, even legal positivists will generally accept that certain formal procedural requirements (hence values) are necessary for legal validity (if only because they are necessary for a system of rules to be a coherent system of rules at all). However, in some legal systems, specific substantive values will come to be so enshrined in the system that, in these societies at least, conformity with these values will be seen to be necessary for conformity with the rule of law. Such values will normally be enshrined in written constitutions, but their general characteristic is that they will be viewed as fundamental principles of law, with which all other laws and public, including state, actions must conform. This is characteristically the case with the ECHR in Europe and those values (which include those of the ECHR) that the European Court of Justice has recognised as fundamental principles of EC law.
- (3) Other purposes and values of the law are not so fundamental. They are contingent (and wholly optional) for legal systems to pursue.

We suggest that fictions that serve to promote conformity with legal purposes are not to be regarded as legal fictions, provided that the fictions do not distort or fictionalise essential legal values (procedural or substantive). Those that do are not only fictions, but wholly reprehensible and not to be countenanced. The fiction of deemed consent in the HTA falls into this category (involving violations of the rule of law at both of the levels we have identified) and merits Bentham's vituperative remarks. The fiction involved³² in the *Pro-Life Alliance* case, by our reasoning, does not fall into this category and Blackstone's attitude towards them seems more appropriate.

We will now try to apply and expand this analysis by looking at a number of cases in patent law.

Determination of Genetic Sequences in Nature as Inventions

It is a general principle of patent law that patents cannot be awarded for mere discoveries.³³ This is encapsulated in Article 5(1) of the Directive 98/44/EC on Biotechnological Inventions, according to which,

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

However, according to Article 5(2) of the same Directive,

An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

What appears to be the crucial difference as to whether a gene sequence is patentable or not, is the process of isolation.³⁴ Once the identification, purification and classification has resulted in the isolation of the gene sequence by a technical process, the subject matter is an invention and not a discovery. Where biological material is concerned this will almost certainly be the case in any given situation.³⁵

In the present context, this raises the question, 'Is it a legal fiction to consider gene sequences that are determined by state of the art methods as inventions when the sequences themselves are not novel but are identical to those occurring in nature, and have indeed simply been isolated from nature?'

The terms 'discover' and 'invent' are closely related. Indeed, according to Merriam-Webster's Dictionary of English Usage,³⁶ the original meaning in English of 'invent' is 'to come upon, find, or discover'. However, the terms were later distinguished from each other. According to Hugo Blair,³⁷ '*[d]iscover* differs from *invent*. We *discover* what before existed, though to us unknown: we *invent* what did not before exist'. In such terms, which represent central modern usage³⁸ '*discover*' means to 'find something existing that was not known before'. '*Invent*' means 'to create' or 'to originate'. The determination of a gene sequence existing in nature would be a discovery and could not possibly be an invention. Nevertheless as Merriam-Webster's Dictionary further explains, there are uses of 'discover' that do not presuppose prior existence of what is discovered.



So, more generally, 'to discover' is '[t]o find out, to obtain the first knowledge of, to come to the knowledge of something sought or before unknown'. But, even on this basis, it remains a fiction to regard the determination of a gene sequence occurring in nature as an invention rather than a discovery.

However, bearing in mind the terms of our preceding analysis, this does not make this construction a legal fiction as against a fiction for the purposes of the law. If the purpose of patent law is to grant a certain kind of protection to particular entities and it is necessary to construe terms so as to ensure that protection, then as long as the law itself does not prohibit such a construction, the fiction is not a legal fiction. So, the matter must be referred to the purposes of patent law.

Historically, the purpose of granting a patent was to reward inventors, understood as creators, for their inventiveness (creativity). This was a natural right and accords with the views on property rights of philosophers such as Locke.³⁹ Later, however, the rationale shifted. At first the shift was subtle. The purpose became, primarily, to prevent the injustice of permitting those other than the inventor from profiting from the labour of the *inventor* without having incurred similar costs. Bentham argued that because an invention involved a great deal of time, money and effort and also included a large element of risk, the exclusive use of the invention must be reserved for a period of time for the inventor.⁴⁰ More recently, however, the rationale appears to be based on economic theories such as those put forward by Nelson and Mazzoleni.⁴¹ These authors seek to justify the patent system as a way of creating incentives for persons to invest money in the production of useful products by protecting their investment from exploitation by others.

We should note that these rationales have implications for the conditions under which patents are to be granted. In particular, it is clear that if the purpose of a patent regime is merely to create incentives for investment then there is no need for inventiveness to be a condition of patent protection. Thus, if the purpose of patent law is taken to be this, there should be no need to fictionalise certain discoveries as inventions because discoveries should be patentable. But conversely, if the law insists on inventiveness as a condition for protection, then the rationale cannot simply be the need to create incentives for investment.

Given that the law (at least Directive 98/44/EC) clearly intends what would normally be thought of as discoveries to be patentable, the logical implication is that the purpose relative to which we must determine whether or not a fiction is involved here, is that of investment protection.⁴² Relative to this, the fiction is not a legal fiction, but a fiction for the purposes of the law. However, this does

not render it altogether harmless in this case. For, the fact that this implies that inventiveness need not be a condition of patent protection renders the law confusing and opaque. This is not necessary. It can and should be remedied by either creating a new intellectual property right (a 'discovery right'), or by dropping inventiveness as a condition of patentability.⁴³

The patentability of animal varieties

According to the first subparagraph of Article 53(b) EPC, European patents shall not be granted for.

Plant or animal varieties or essentially biological processes for the production of plants or animals

In the *Oncomouse* case,⁴⁴ which concerned a patent application for a genetically engineered mouse to be used as a model for cancer research, this provision was used by the Examining Division of the European Patent Office (EPO) to reject the application, on the grounds that the exclusion of 'animal varieties' is an exclusion of animals as such.⁴⁵ One of the reasons given was that the terms used in the three official languages of the EPC (German, English and French), viz. 'tierart', 'animal variety' and 'race animale' are not equivalent in anything like their scientific meanings. The Examining Division did not expand, but it is possible to construct its reasoning in the following way. In its scientific meaning, 'tierart' is equivalent to 'species' in English, 'animal variety' has no formally recognised scientific meaning following the International Code of Zoological Nomenclature agreed at the XVth International Congress of Zoology in London held in July 1958 and informally refers to a sub-sub-species category, whereas 'race animale' is equivalent to 'breed'. However, 'tierart', 'animal variety' and 'race animale' also carry everyday usage meanings, in which they simply refer to types of animal in general regardless of level of classification. Because Article 177(1) of the EPC states that the three official languages are to be given equal force, the everyday meaning must be attributed.

On appeal, however, the Board of Appeal requested the Examining Division to reconsider its ruling.⁴⁶ When it did so, the Examining Division decided that the exclusion of 'animal varieties' etc. only amounted to an exclusion of claims that are to a specific species of animal or a specific sub-species or sub-sub-species of animal. However, if the patent is intended to cover a higher level of classification (e.g., a genus) then the invention is not excluded.⁴⁷



In effect, if the oncomouse is described as a particular species of mouse then the patent may not be granted. On the other hand, if it is described as a member of the rodent genus then the patent is not excluded by Article 53(b).

In evaluating this reasoning, it must be borne in mind just how artificial this is. For it is clear that every rodent will also be a member of a particular species, a member of a particular breed, etc. Consequently to regard the claim as not being a patent on a species or lower classification by virtue of being a patent worded in terms of being on a member of a genus, is at least a fiction (and is surely a contradiction, as it is not the term that is being patented but the animal). What undoubtedly drives this is the general policy operated by patent law that exceptions to patentability are to be construed as narrowly as possible, so that if there is any interpretation possible that evades the exception then that interpretation must be given.⁴⁸

There must, however, be limits to this, otherwise all exceptions to patent law are empty. So, bearing in mind that purposive construction must accord not just with general policy intentions but also with specific intentions of the drafters of the law, it should surely have been considered by the Examining Board that if the intention of the drafters was to exclude only invented species (and lower classification) then they would have referred to 'species' in English, 'espèces' in French and 'tierarten' in German. After all, these are equivalent in meaning, are scientifically recognised classifications, and patent law does generally assume that words are to be given their scientific meanings.⁴⁹

Cells as Microbiological Entities

According to the second sub-paragraph of Article 53(b) EPC, the first subparagraph 'does not apply to microbiological processes or the products thereof'. Consequently, the bar on patenting animal (and plant) varieties (and set by the first sub-paragraph of Article 52(b) EPC) does not apply if the animal variety is a microbiological process or the product thereof.⁵⁰ This is obvious from the wording, though it is interesting to note that the Examining Division of the EPO in the Oncomouse case did not originally consider that oncomice, as an animal variety, would be patentable even if they were produced by a microbiological process.⁵¹

Now, according to Rule 23(b)(6)

'Microbiological process' means any process involving or performed upon or resulting in microbiological material.⁵²

The patent offices have interpreted the exception to this subparagraph contained in the second sub-paragraph of Article 53(b) to permit cell-lines (whether of animal or human tissue) as well as types of fungi to be patented.⁵³ This is odd because it requires cell-lines and fungi to be construed as animal or plant varieties or essentially biological processes for the production of plants or animals. Otherwise the first sub-paragraph of Article 53(b) presents no bar to their patentability. Fungi may be so interpreted readily, though only if animal/plant varieties carry everyday usage rather than scientific meanings. But it is difficult to see the basis for interpreting cell-lines as animal/plant varieties without extending this reference to cover all living biological material. A fiction appears to be involved here which is certainly not a fiction for the purposes of the law (in the case of cell-lines) as it does not appear to be necessary to serve any legal purpose, or (in the case of fungi) is only necessary when a reading of the first sub-paragraph is given that the EPO has rejected (as we have already seen from the *Oncomouse* case).

But let us pass over this and suppose that there are no complications of this sort to disentangle. If so, then the question arises as to whether or not fungi/cell-lines are microbiological processes or the products of microbiological processes. On Rule 23(b)(6) fungi are surely not microbiological processes. However, they might, if genetically modified by insertion of genes into individual cells, be products of microbiological processes, while cell-lines clearly are products of microbiological material (as they are grown from individual cells) which are microbiological material (i.e. biological material of a microscopic size). No fiction, then, is involved in reading cell-lines or fungi produced by specific means as microbiological processes for the purposes the second sub-paragraph of Article 53(b).

We have looked at these examples of purposive construction in patent law in order to illustrate the usefulness of the distinction we have made between legal fictions proper and fictions for the purposes of the law. This process also shows clearly how much purposive construction is relative to the purposes of the law. And this serves to explain why purposive construction is likely to be a controversial matter; for determining the purposes of (the) law is not always as clear cut as it might be. In the *Pro-Life Alliance* case, the purpose is clear (and given in the preparation and passing of the HFE Act). In the case of deemed consent, the purpose may be referred to the interpretive role of the HRA. In the patent law cases, however, the purposes of the law are not given in the same way. The purposes of patent law appear to have changed over time and this has been a process driven by industrial practice and the patent system rather than by legislation. Patent law, as with all areas of law, cannot remain static. It has had to respond to changes in technology, especially to the



rapid advances in biotechnology seen in the last 20 years. Alongside these advances, there have been wholesale changes in attitude as to the justification of the patent system, where economic considerations are often considered paramount. However, the patent system has often employed legal semantics to interpret existing law to reach a desired outcome⁵⁴ that reflects these changes rather than acceptance that the law needs to be amended. What has transpired has not merely been a lack of clarity and a degree of legal uncertainty, but has involved distortion of the law to an extent that is not compatible with the rule of law.

Concluding Remarks

An account of legal fictions that has achieved classic status is provided by Lon Fuller⁵⁵. However, our argument has implications for this account, and some remarks about this are called for. According to Fuller, a legal fiction has three elements: falsity, utility and dangerousness. Legal fictions are ‘false statement[s] recognised as having utility’⁵⁶ Furthermore, Fuller believed that legal fictions are inherently dangerous in that they can be carried to extremes if put to uses not intended by their authors or if taken too seriously as statements of fact rather than as useful metaphors.⁵⁷

It is clear that issues arise when we delve into the test for truth or falsity, or into the criteria for utility or dangerousness. While this is not the time to develop a comprehensive analysis of these tests and criteria, it must be noted that our proposed distinction cuts across the idea that ‘the most useful test for falsity [in connection with the idea of a legal fiction] is to ask whether the statement asserts or implies a fact that would be regarded as false by a[n] ordinary layperson, standing outside the legal system and looking in’,⁵⁸ which some commentators advocate. Secondly, it cuts across the notion that the tests for utility and truth are entirely independent (at least where legal definitions are, as we have argued, to be given purposive constructions driven by a commitment to legal/moral values). Thirdly, our account implies that what it classifies as legal fictions properly speaking (i.e., fictions about the law), are not merely dangerous, but necessarily inimical, whereas fictions for the purposes of the law are inimical only when the purposes of the law itself are inimical.

NOTES

*We would like to thank the anonymous reviewer for thought provoking comments which have helped us to sharpen some of our analysis.

1. *R (on application of Quintavalle) v Secretary of State for Health* v [2003] UKHL 13.
2. *Commentaries on the Laws of England*, 260.
3. Jeremy Bentham, *Works* 77 (Bowring ed. 1843)
4. Jeremy Bentham, *Works* 283 (Bowring ed. 1843)
5. The discussion of the *Pro-Life Alliance* case draws heavily on Deryck Beyleveld and Shaun Pattinson, 'Globalisation and Human Dignity: Some Effects and Implications for the Creation and Use of Embryos'. In Roger Brownsword, ed.: *Global Governance and the Quest for Justice Vol 4 Human Rights* (Oxford and Portland, Oregon: Hart Publishing 2004), pp. 185–202. Some parts of that article are reproduced below, with the permission of the co-author of that piece.
6. s.1(1)(a).
7. s.1(1)(b).
8. *R (on application of Quintavalle) v Secretary of State for Health* [2001] EWHC 918.
9. [2002] EWCA Civ 29, para. 45.
10. See [2003] UKHL 13, paras. 14 (Lord Bingham), 20 (Lord Steyn), and 37 (Lord Millet).
11. *Ibid*, para 14.
12. *Ibid*, para 26.
13. *Ibid*, para 45.
14. *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London, HMSO, 1984) (Cm 9314) (Report of the Warnock Committee) para 11.7
15. We do not think that this overstates the case. To say that this is a legal fact is to say that to interpret SCNT as a process of fertilisation is not merely a *valid* reading of the Act, but *the only valid* reading.. But this it surely is, as the wording of the Act, according to which embryos are produced by fertilisation *logically* implies that SCNT is a process of fertilisation once SCNT produced embryos are held (purposively) to fall under the Act. If the Act defines embryos as produced by fertilisation and at the same time requires SCNT embryos to fall under the Act, then the Act must, in consistency, regard SCNT embryos as produced by fertilisation. To say that it is a legal fact that (under the Act) SCNT is a process of fertilisation is to say no more and no less than that no other construction is consistent with the legal facts (true statements) that SCNT embryos are to be protected and that what is to be protected is produced by a process of fertilisation. This, of course, does not imply that new legislation ought to treat SCNT as a process of fertilisation (as against, e.g., defining embryos as beings with specified characteristics regardless of the way in which they were created). But this, in turn, does not imply that, in the context of the present Act, it cannot be properly said to be true (hence a fact) that SCNT is a process of fertilisation.
16. s.12(c) and Sch 3, para 6.
17. For a full discussion of the *Pro-Life Alliance* case see Beyleveld and Pattinson, *op cit*, n 5.

In May 2007, the UK Government issued the Human Tissue and Embryos Bill, which is intended to revise the HFE Act 1990. In this Bill, 'fertilisation' retains its ordinary meaning. SCNT-produced embryos, we think, are intended to be brought within the remit of the Act by defining 'an embryo' to include to 'an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo' (see clause 14(2), modifying s.1(1), and clause 17(2), introducing s.4A(7)). Apart from a degree of avoidable circularity (not helped by dropping the previous reference to an embryo being a fertilised egg), this is not precise enough to avoid problems. Normally, the process of SCNT is

viewed as one in which a somatic nucleus is introduced into an *enucleated* egg, which is not an egg. Thus, it could be argued that SCNT is not a procedure in which *an egg* is undergoing a process capable of resulting in an embryo. Granted, if we refer not to SCNT, but to the enucleation of the egg and SCNT as the process it is undergoing, then the problem is removed. Alternatively, it might be argued that SCNT should be given a broad interpretation under which it includes the enucleation step. The latter, however, requires a purposive construction, which is a matter for authoritative interpretation by the courts, and the Bill is intended to make that unnecessary. On the other hand, the former option leaves it not entirely clear when an embryo has been created. Is it when the egg is enucleated with the intention of inserting a somatic nucleus, or only when the somatic nucleus is being inserted? To be sure, the Bill contains provisions giving the Secretary of State the power to modify the definition of 'embryo', 'eggs', 'sperm' and 'gametes' to take account of developments in science and medicine (see clause 14(5), inserting s.1(6) and s.1(7)(b)), which would enable the uncertainty we point out to be dealt with without recourse to the courts. However, at this stage, this should be avoided in the Bill itself. This is particularly so because the unclarity we allude to is not a result of scientific or medical advance, but of avoidable unclarity in drafting.

In any event, should the legislature follow the Bill and choose not to define fertilisation as any process by which an egg is made capable of producing an embryo, this would not affect the validity of our purposive reading of the existing Act, anymore than the validity of this reading affects the viability of the general line taken by the Bill, which is not a purposive reading of the existing Act, but a proposed revision of it.

18. s.3(2).
19. By so characterising deemed consent here, we are asserting that legal fictions are not merely devices employed by courts in interpreting statutes. They can be deployed by legislators in statutes themselves.
20. The principal impetus for the HTA 2004 was two scandals involving the use of tissue without consent at Bristol Royal Infirmary and Alder Hey Children's Hospital. Liverpool. As paragraph 4 of the Explanatory note to the HTA 2004 makes clear, the Act makes 'consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.'
21. See Lon L. Fuller, *The Morality of Law*, 2nd edition. (New Haven: Yale University Press 1969) pp. 65–70 and 81–91.
22. While consent is not sufficient for any actions that fall under the HTA to be lawful (e.g., commercial transactions in organs), it is sufficient for storage for a use for a purpose specified in Schedule 1 Part 1 of the Act to be lawful.
23. See, e.g., *W v Egde* [1990] 2 W.L.R. 471, and the Public Health (Control of Disease) Act 1984.
24. See s.3(1).
25. There is no European Court of Human Rights case law directly on this point that we are aware of. However, the European Court of Human Rights has consistently upheld the view that the use of sensitive personal data engages Article 8(1) (see, e.g., *Z v Finland* (1998) 25 E.H.R.R. 371.). Since the Court operates with a very broad concept of the right protected under Article 8(1), according to which this article covers attacks on physical or mental integrity, moral or intellectual freedom, honour or reputation; use of name, identity or likeness; being spied upon, watched or harassed; and disclosure of confidential information (see, e.g., J. Velu, 'The European Convention on Human Rights and the Right to Respect for Private Life, the Home and Communications', in A. H. Robertson (ed.), *Privacy and Human Rights* (Manchester: Manchester

University Press, 1973) 12–128 at 92), and, indeed, Article 8(1) has been said to give a right to all constituent parts of an individual's personality that are not protected by other rights in the Convention (see L. G. Loucaides, 'Personality and Privacy Under the European Convention on Human Rights' *British Yearbook of International Law* LXI (1990) 175–197 at 196), it is difficult to see how the use of human tissue might not be covered by Article 8(1).

26. In relation to the use of sensitive personal data, see, e.g., *M.S. v Sweden* (1999) 28 E.H.R.R. 313, paras 34–35.
27. These are, specifically, that interference with the right provided by Article 8(1) be 'in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

But, in any case, non-compliance with the ECHR (except in Scotland, on which see Iain Jamieson, 'Relationship between the Scotland Act and the Human Rights Act' *Scots Law Times* (2001) 5: 43–48) does not invalidate legislation. For, while courts may make a declaration of incompatibility in connection with offending primary legislation or secondary legislation that is incompatible on account of its driving primary legislation, they cannot declare it invalid on such a ground (s.3(2)).

28. Some might think that the incongruity we focus on here is unnecessarily theoretical. Surely, they will say, there is an obvious incongruity between the stated objectives of the Act to 'make consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue' (Explanatory Notes para 4). However, not only is it unnecessary to refer to the Explanatory notes, for the Act (s.1) itself by making various activities lawful with consent makes consent the fundamental principle, such a thought is too simplistic. Such incongruity is relevant when dealing with a judicial construction of the Act that deems consent when it is not given per the Act's purposes. But here it is the Act itself that deems consent to be given when it is not given in ordinary parlance. If this is to be construed as a legal fiction (and not merely as a fiction for the purposes of the law), it must be so in terms that involve disutility in relation to fundamental legal values that the Act must respect.
29. See e.g. Special issue of the *Human Rights Quarterly*, Vol. 7 (1985), pp. 1–157. (The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights on pp. 3–14) and *Loizidou v Turkey*, 310 Eur.Ct.H.R. (ser A) at 27, 31 (1995): 'the convention is a constitutional instrument of European public order' (ordre public).
30. See, for a critical commentary, Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), esp. p.47 (the Gifford Lectures delivered at the University of Edinburgh, 2001).
31. See Deryck Beyleveld and Roger Brownsword, *Consent in the Law* (Oxford: Hart Publishing, 2007) esp. Chapter 8, where specific fallacies of necessity and sufficiency are identified and analysed.
32. Though not adopted by the House of Lords.
33. Article 52(2)(a) of the European Patent Convention declares that discoveries, scientific theories or mathematical methods are among the subject matter or activities that are not patentable inventions. The US Patents Act allows patents for the invention or discovery of any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof. This formula does not attempt a distinction between invention and discovery, but instead insists that as well as being new, the subject-matter of a patentable invention must be useful (SS.101–103).

34. Recital 21 of Directive 1998/44 EC.
35. See for example *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9 and *Genentech Inc's patent* [1989] RPC 147 for the distinction between discovery and invention of gene sequences.
36. *Merriam-Webster's Dictionary of English Usage* (Springfield Publishing, Springfield, USA 1994) p348.
37. Hugo Blair, *Lectures on Rhetoric and Belles Lettres* (Kay & Co Publishing, Philadelphia 1849).
38. See Roget's Thesaurus of English Words, Publisher: Penguin Books Ltd; New Ed edition 2000, Middlesex, p 225.
39. See Locke, J. *The Second Treatise of Civil Government* 1690, reprinted (Barnes & Noble, Boston 2004).
40. Bentham, J. *Manual of Political Economy*, reprinted in Stark, W. (ed) (1952) *Jeremy Bentham's Economic Writings*, vol. 1, Allen & Unwin, p71.
41. Nelson, R. and Mazzoleni R. 'Economic Theories About the Costs and Benefits of Patents' in *Intellectual Property Rights and Research Tools in Molecular Biology* (National Academic Press, Washington 1997).
42. This is explicit in the Directive itself, for Recital 2 has it that 'in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable.'
43. There is no incongruity between our position here and our position (expressed in n. 28 above) that the stated aim of s.1 of the HTA 2004 (of making the obtaining of consent central) is, by itself, insufficient to determine that the deeming of consent in Regulation 3(2)(a) of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations is a fiction. Our *general* position is that, *provided more important legal values are not compromised thereby*, the *clear* purpose of an Act is the relevant standard for determining legal fact or fiction. In line with this, in relation to the HTA 2004 (and subordinate provisions), we maintain that what consent means in the Act can only be understood in terms of considerations deriving from the ECHR because of the status of the Human Rights Act 1998 in UK law. In line with our general position also, in relation to the Directive, we claim that the purpose of patent *law is not clear*. If it were solely to give protection to investment then patents should be granted whenever this would protect investment regardless of what process led to the product or process being claimed. On the other hand, if further conditions are placed on granting a patent, then this is not consistent with the sole purpose of patents being to protect investments.
44. *T19/90 Oncomouse/HARVARD*, O.J. E.P.O.(1990) 476
45. *ibid.* at 7–8
46. *Harvard/Oncomouse* [1990] EPOR 501
47. See OJ EPO 10/1992, 588 at 590.
48. The narrow interpretation of all exclusions from patentability can be exemplified by the last part of section 1(2) of the UK Patents Act which states '...provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing *as such*' (emphasis added). The effect is that the exclusion only operates if the patent application is directed towards the excluded thing itself. Hence exclusions are interpreted narrowly.
49. Adcock, M.D. and Llewelyn, M. 'TRIPs and the Patentability of Micro-Organisms' *Bio-Science Law Review*, (2001) vol 4, issue 3, 91–101
50. See EPO Board of Appeal [1990] 7, EPOR 501, at 512
51. [1990] 1 EPO 4, at 9
52. See decision of the Enlarged Board of Appeal G1/98 Annex 1]



53. See e.g., Schertenleib, D., *The Patentability and Protection of Living Organisms in the European Union*, EIPR 2004 26(5), pp. 203–213 and Adcock, M.D. and Llewelyn, M., *TRIPs and the Patentability of Micro-Organisms*. *Bio-Science Law Review* (2001) vol 4, issue 3, 91–101
54. See, for example, the *Oncomouse* case with regards to animal varieties and the *Novartis* case (G1/98) for the discussion on the scope of the exclusion of plant varieties.
55. See Lon Fuller, *Legal Fictions* (Stanford CA: Stanford University Press 1967).
56. *Ibid.* 9.
57. *Ibid.* n. 19, 370.
58. Niki Kuckes, 'The Useful, Dangerous Fiction of Grand Jury Independence' *American Criminal Law Review* vol. 41/1 (2004) 3.